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510(k) Summary

Intercept™ Esophageal, Urethral and Vascular Internal MR Coils
Philips 1.5T Compatible

Common/Classification Name: Accessory to
Magnetic Resonance Diagnostic Device, 21 CFR 892.1000

Surgi-Vision, Inc.
20 Firstfield Road, Suite 200
Gaithersburg, MD 20878

Contact: Nancy E. Taylor, Prepared: March 11, 2002

A. LEGALLY MARKETED PREDICATE DEVICES

The **Intercept™ Esophageal Internal MR Coil** is substantially equivalent to the Surgi-Vision Esophageal Stylet Coil, which was cleared for marketing on March 14, 2000, in premarket notifications K994436. The **Intercept™ Urethral Microcoil,** is substantially equivalent to the Intercept Urethral Microcoil, which was cleared for marketing on August 31, 2001 in premarket notification K011781. The **Intercept™ Vascular Internal MR Coil** is substantially equivalent to the Surgi-Vision Guidewire Coil, and cleared for marketing on February 2, 2001 in premarket notification K003436. This submission also represents notification of the change from SV coils to Intercept Coils. The predicate devices are compatible with the GE 1.5T system and the current submission requests clearance on the identical product, with a Philips compatible connector.

B. DEVICE DESCRIPTION

The **Intercept™ Internal MR Coils** are intracavitary specialty coils for use in MR imaging of the anatomical regions surrounding a body cavity. The signals picked up by the coil are conducted through a small coaxial cable and interfacing network to a connection with the standard surface coil connector for MRI systems. The coil is insulated with polymeric housing that protects is from contact from body fluids.

C. INTENDED USE

The **Intercept™ Internal MR Coils** are recommended for high-resolution Magnetic Resonance Imaging of internal anatomical structures. The single use, disposable coils were designed to be inserted into body orifices of the patient during MRI scans in order to obtain improved image quality in the anatomical regions surrounding the coil. The unique coil shapes facilitate orientation of the coils to the anatomy. These products are to be used with a 1.5T Philips MRI system.

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D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Intercept™ Internal MR Coils** have identical, indications for use as the legally marketed predicate devices.

The **Intercept™ Internal MR Coils** have the same technological characteristics as the predicate devices. Both proposed and predicate devices have an electronic matching circuit, a connecting coaxial cable, and an intercavitary probe with a radiofrequency receiving coil. However, there are differences in the scanner systems that make it desirable to provide performance data to assure substantial equivalence. Such performance data are available and do demonstrate substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

See Section D, above.

F. TESTING

Surgi-Vision carried out testing and/or analysis of the **Intercept™ Esophageal Internal MR Coil** that addressed the following issues:

1. Possibility of excess RF heating
2. Possibility of increased susceptibility of patients to peripheral nerve stimulation
3. Imaging performance
4. Mechanical Testing

POSSIBILITY OF EXCESS RF HEATING

The primary safety issue for the **Intercept™ Esophageal Internal MR Coil** is the potential for excess heating of tissue near the coil by MRI system's RF power. Surgi-Vision carried out a study in a phantom that shows that the change in temperature is within the same range with the coil in place as without it.

The results of the heating experiments demonstrate that there is no excess heating when the coil is positioned in a phantom that is representative of clinical conditions. The change in temperature observed during use of the coil is not significantly different then that observed without the coil. Finally, the imaging performance demonstrates enhanced resolution of aortic regions visualized from the esophagus. The results of the testing demonstrate that there are no safety problems for imaging of a patient using the **Intercept™ Esophageal Internal MR**

Coil if the instructions for use are followed and the change in temperature observed during use of the coil is within an acceptable range (< 2 degrees C in the trunk).

POSSIBILITY OF INCREASED SUSCEPTIBILITY TO NERVE STIMULATION

The experiments done previously to determine current leakage by the MRI pulsed gradient field demonstrate that there is no possibility of increased susceptibility of patients to peripheral nerve stimulation. This remains true despite a change from the GE to the Philips system. A copy of this report is included in this 510k.

IMAGING PERFORMANCE

The Surgi-Vision coil functions like any other specialty MRI coil and it is indicated for general diagnostic imaging. Therefore, a series of images were taken using the coil in a volunteer illustrating its use in the esophagus on the Philips 1.5T MRI system.

MECHANICAL TESTING

The Surgi-Vision coils have undergone mechanical testing and the results on the Esophageal Coil were provided. Since the coils are identical to the original Surgi-Vision Esophageal Stylet Coil, the same results are presented. The bonds between the connector/coaxial connector and connector/Introducer sleeve have displayed strengths in excess of the required 1lb/f.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2002

Ms. Nancy E. Taylor
CEO/President
Surgi-Vision, Inc.
20 Firstfield Road, Suite 200
GAITHERSBURG MD 20878

Re: K020790
Trade/Device Name: Intercept Esophageal Internal MR Coil
Intercept Urethral Internal MR Coil
Intercept Vascular Internal MR Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: March 11, 2002
Received: March 11, 2002

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K020790

Device name: **Intercept™ Urethral Internal MR Coil**

Indications for Use:

The **Intercept™ Urethral Internal MR Coil** is recommended for high-resolution Magnetic Resonance Imaging of the male and female urethra and surrounding tissue. The single use, disposable coil was designed to be inserted in the urethra of a patient during MRI scans in order to obtain improved image quality in the anatomical regions surrounding the urethra and including the prostate in males. The flexible coil facilitates placement of the coil in the anatomy. This product is to be used with a 1.5T Philips MRI system. The signals picked up by the coil are conducted through a small coaxial cable to a connection with the standard surface coil connector for MRI systems. The coil and cable are completely sealed inside the insulating layer.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Legemon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020790

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K020790

Device name: **Intercept™ Vascular Internal MR Coil**

Indications for Use:

The **Intercept™ Vascular Internal MR Coil** is recommended for high-resolution Magnetic Resonance Imaging of the peripheral vasculature. The single use, disposable coil is designed for insertion into an artery or vein of a patient during MRI scans in order to obtain improved image quality in the peripheral vasculature. The flexible coil facilitates placement of the coil in the peripheral vascular anatomy. The coil would most commonly be used through femoral artery access similar to .035" guidewires currently in use. The handling characteristics of this device are familiar to vascular interventionalists thereby facilitating integration into their practices.

This product is to be used with a 1.5T Philips MRI system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020790